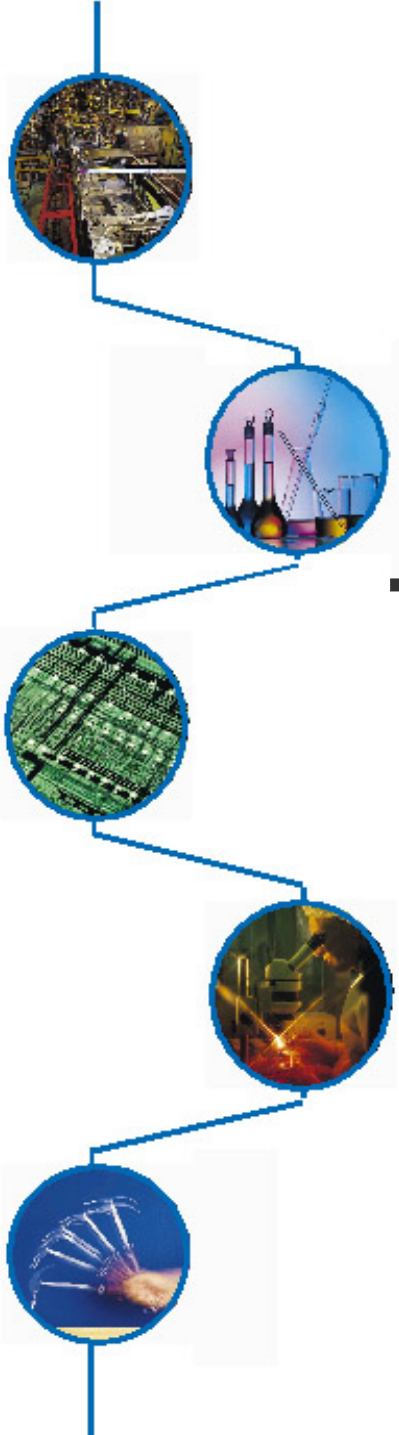# The Role of the Technical Expert in ANSI's TCB Accreditation Program

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Overview

- The primary roles of the TE are:
  - To assist the lead assessor in highly technical areas of the assessment
  - To prepare NCCARs for non-compliance in technical areas
  - To prepare a report detailing the TE's findings for attachment to the assessment report prepared by the lead assessor
  - To review corrective action proposals of the CB and provide the lead assessor with recommendations on the appropriateness and completeness of the proposals

Preparation

- Review last assessment report, if applicable, to develop an understanding of the certification bodies processes

- Review the email complaints generated by the FCC regarding issues that occurred over the past 12 months

- Discuss any concerns or issues that you may have with the lead assessor prior to arriving at the certification bodies' facilities

- Prepare an agenda to organize the time on-site

On-site Assessment Opening Meeting

- Agenda for all on-site assessor activities
- Discussion of assessment process
- Expectations of certification body and assessors
- Approximate schedule for specific activities such as expert knowledge interviews and laboratory demonstrations
- Overview of the certification bodies' processes
- Overview of certification bodies' facilities and short tour of facilities

On-site Assessment Breakout

- Lead assessor typically starts interview with appropriate certification body staff regarding ISO/IEC Guide 65 in general and specifically the CB's quality system

- TE starts the interview process with the evaluators/reviewers regarding their evaluation processes, systems and technical knowledge

- Certifiers are also interview, to ensure that they have basic knowledge of the certification system and the regulatory bodies requirements

On-site Assessment

- Review of certification processes – full assessment
  - FCC – IC - IDA
    - Review application process
      - How is application information provided to the TCB
      - Who has access
      - Review security of applicant data
      - Does the TCB have a flow chart describing the processes
      - Does the process provide for interchanges with the applicant
      - Are these interactions documented in the application file
      - Does the TCB have a check-list for each product it certifies
      - cont.

On-site Assessment

- – Does the TCB have the proper procedures in place to publish its certifications
- – Does the published certification have the appropriate information required by the regulatory body
- – Does the TCB have an appropriate process in place for storing the application information for the appropriate time period

➢ Repeat Day 1 evaluations for each economy as required

On-site Assessment

- How are the regulatory bodies rules and regulations provided to the TCB reviewers
  - Electronic
  - Paper
- Dissemination of regulatory changes
  - Procedures for updating copies of regulations, standards and test methods
  - Time line for updating and implementing these changes
- Internal audits and management reviews
  - Addressing audit complaints from the FCC
  - What were the issues addressed in the email complaints
  - Did the TCB adequately respond to these issues
  - What procedures did the TCB put into place to eliminate these issues from recurring

On-site Assessment

- Personnel
  - TCB organization chart
    - Qualifications of administrative staff – knowledge of electronic filing systems
    - Qualifications of reviewers (technical and admin)
    - Qualifications of certifiers
  - Attendance at regulatory body training and at other information distribution forums
    - Regulatory body training sessions
    - Teleconference calls
    - Other forum

On-site Assessment

- Personnel (cont.)
  - Knowledge of FCC requirements for certification
    - Annotated check sheet
  - Knowledge of test methods and test instrumentation
    - Core testing demonstration in the CB's laboratory of each reviewer capabilities
- Repeat Day 2 evaluations for each economy as appropriate

On-site Assessment

- Review of certification packages
  - Prepare comments on application and evaluation packages provided by the TCB for two devices
  - Review comments prepared above with TCB reviewers
- Repeat the above review for each economy
- Review ANSI check list to insure all TE items on the assessment have been accomplished
- Prepare information for discussion with lead assessor regarding possible NCCARs

On-site Assessment

- Review possible NCCARs with lead assessor
- Prepare NCCARs as appropriate
- Participate in Closing Meeting
  - Respond to questions from the TCB staff
  - Summarize TE findings for the TCB staff

Surveillance Assessment

- On-site assessment may consist of a full assessment (or re-assessment) for one economy and a surveillance assessment for another economy

- Typically a surveillance assessment is less detailed and looks at important events for a particular economy during the past year

  - FCC email complaints
  - Policy changes by the regulatory body, i.e.
    - TCB prohibited from certifying certain devices
    - Changes to the exclusion list
  - Rule changes during the past year
  - Administrative changes, i.e.
    - Computer upload formats changes

ISO/IEC 65 Clauses – Surveillance Assessment (cont.)

- 4.3 – Operations ISO/IEC 17025
  - Purchasing CSP services (4.6 ISO/IEC 17025)
  - Test Methods and Method Validation (5.4 ISO/IEC 17025)
  - Equipment (5.5 ISO/IEC 17025)
  - Measurement Traceability (5.6 ISO/IEC 17025)
- 5.2.2 Staff
  - Competency
  - conflict of interest including prior and present association with suppliers of products.
  - Contract compliance with rules of TCB,
  - Confidentiality of suppliers

Technical Topics for TCB, IC, and IDA

- Scope of 17025 Accreditation
  - Appropriate Standards List
  - Correct revisions of those Standards
- Technical Reviewer and Certifier Competence
- Review of FCC set-asides and/or IC and IDA certification files
- Surveillance Files
- Certificates

ISO/IEC 65 Clauses – Surveillance Assessment (cont.)

- 6 Changes in Certification Requirements
  - Including updating of forms and processes (4.5.3 g, ISO/IEC Guide 65)
  - Short term confidentiality
- 8 Applications
  - Applicants rights (8.1.1)
  - Duly authorized representative of the applicant (8.2.1)
- 9.3 Assigned personnel qualified for the evaluation and check for conflict of interest
- 10 Evaluation – against all certification criteria

ISO/IEC 65 Clauses – Surveillance Assessment (cont.)

- 11 Evaluation Report
  - Report of findings of conformity with ALL certification requirements (11 a)
  - Full report on the outcome of the evaluation, given to applicant and certifier (11 b)
- 12.3 c Effective date of certification (IC REL)
- 13 Surveillance Files / Records
  - CB shall require supplier to inform of any changes (13.2)
  - FCC Surveillance requirements

Assessment of Technical Reviewers / Evaluators Competence

- ANSI Technical Checklist
- Review of Evaluation Reports
- FCC Interactions
- HR File (training, confidentiality, and conflict of interest)
- Demonstration of instrumentation competency (RF Power, PSD, Bandwidth)
- Knowledge of BW limitations

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